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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,684	03/19/2004	Takeshi Sakamoto	58748 (70342)	8548

7590 04/08/2005
Edwards & Angell, LLP
P.O. Box 55874
Boston, MA 02205

EXAMINER

TSAY, MARSHA M

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/805,684

Applicant(s)

SAKAMOTO ET AL.

Examiner

Marsha M. Tsay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 192-211 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 192-211 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-191 are cancelled by Applicant. Claims 192-211 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 192-197, drawn to an isolated protein complex having a first protein that consists of the amino acid sequence depicted as SEQ ID NO. 1-3, 51-54, 115-117, respectively, and having a second protein that consists of the amino acid sequence depicted as SEQ ID NO. 4-26, 55-86, 118-138, respectively, classified in class 530, subclass 350.
- II. Claim 198, drawn to a method for making an isolated protein complex comprising a first protein in contact with a second protein, classified in class 435, subclass 69.1.
- III. Claim 199, drawn to a method for detecting a protein complex containing a first protein FHOS and a second polypeptide, classified in class 435, subclass 4.
- IV. Claims 200-203, drawn to a method for selecting modulators of a protein complex formed between a first protein FHOS and a second protein, classified in class 435, subclass 4.
- V. Claim 204-208, drawn to a method for determining whether a compound is capable of modulating an interaction between a first protein depicted as SEQ ID NO. 1-3, 51-54, 115-117, respectively, and a second protein

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depicted as SEQ ID NO.4-26, 55-86, 118-138, respectively, classified in class 435, subclass 4.

VI. Claims 209-210, drawn to a method for modulating the function or activity of a protein complex in cells of a specific tissue of a mammal, having a first protein interacting with a second protein, classified in class 435, subclass 4.

VII. Claim 211, drawn to a method for screening to identify compounds that activate or inhibit an activity of a protein complex formed between a first protein and a second protein, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein complex, in its entirety, can be isolated from a cell once it is expressed or each of the proteins comprising the protein complex can be expressed and isolated separately and brought together to form the complex in vitro.

Inventions I and III-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a protein complex comprising a first protein

and a second protein and different methods of practice associated with the protein complex. While the protein complex could be used in the practice of Inventions III-VII, the protein complex could be used in more than one patentably distinct method.

Inventions II and III-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a method for making a protein complex and different methods of practice associated with the protein complex. The methods are used for different purposes, directed to different steps, and therefore are patentably distinct each from the other.

Inventions III-VII are patentably distinct each from the other because they are drawn to methods that have different steps and reactants and the steps of one invention cannot be used in the other invention. For example, the steps for detecting a protein complex in a sample cannot be used in a method for modulating the function or activity of a protein complex in a cell.

Upon election of an Invention, Applicants must also elect a single sequence for search that is representative of protein one and a single sequence for search that is representative of protein two in the isolated protein complex. This is not a species election. The protein complex comprises a first protein that consists of the amino acid sequence depicted as SEQ ID NO. 1-3, 51-54, 115-117, respectively, and a second protein that consists of the amino acid sequence depicted as SEQ ID NO. 4-26, 55-86, 118-138, respectively. The protein complex can be made from a multitude of

combinations between the polypeptide sequences that are representative of protein 1 and protein 2. For example, a first protein depicted as SEQ ID NO.1 can form a complex with a second protein selected from SEQ ID NO.4-26, 55-86, 118-138. Each of the polypeptide sequences has a different amino acid structure, function and utility.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 30, 2005



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER